# 510(k)

JUL - 7 2000

## Summary of Safety and Effectiveness

**General Provisions**

The name of the device is:

| Proprietary Name | Common or Usual Name |
|---|---|
| The Cordis TrapEase Permanent Vena Cava Filter with Introduction Kit | Permanent Vena Cava Filter with Introduction Kit |

**Name of Predicate Devices**

The device is substantially equivalent to:

- The LGM - Vena 30 D/U Vena Cava Filter System, B. Braun
- Simon Nitinol Filter/Straight Line™ System and Simon Nitinol Filter™ System, Nitinol Medical Technologies, Inc.
- Stainless Steel Greenfield® Vena Cava Filter, MediTech, Boston Scientific Corporation

**Classification**

Class III.

**Performance Standards**

Performance standards have not been established by the FDA under section 514 of the Food, Drug and Cosmetic Act.

**Indications for Use**

The intended use of the TrapEase Permanent Vena Cava Filter and Introduction Kit is prevention of recurrent pulmonary embolism via percutaneous placement in the inferior vena cava in the following situations:

- Pulmonary thromboembolism when anticoagulants are contraindicated,
- failure of anticoagulant therapy in throboembolic diseases,
- emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced and chronic, and
- recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.

| | |
|---|---|
| **Device Description** | The subject device is a system that consists of a flexible, symmetrical, self-expanding vena cava filter to be deployed in the infrarenal inferior vena cava via a 6F sheathed introduction kit. The filter is designed to trap large, life-threatening emboli and therefore prevent recurrent pulmonary embolism, while maintaining caval patency. The TrapEase filter is packaged in its contrained state within a storage tube. Due to the unique symmetrical design of the TrapEase filter, the introduction kit can be used to percutaneously delivery the filter via either the jugular or femoral veins. |
| **Biocompatibility** | All materials used in the Cordis TrapEase Permanent Vena Cava Filter with Introduction Kit are biocompatible. |
| **Summary of Substantial Equivalence** | The Cordis TrapEase Permanent Vena Cava Filter with Introduction Kit is substantially equivalent to the predicate devices. The equivalence was confirmed through clinical and non-clinical tests and analyses. |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 7 2000

Karen Wilk, RAC
Senior Regulatory Affairs Associate
Cordis Corporation
P.O. Box 4917
Warren, NJ 07059

Re: K000062
Trade Name: Cordis Trap Ease™ Permanent Vena Cava Filter and Introduction Kit
Regulatory Class: II
Product Code: 74 DTK
Dated: May 5, 2000
Received: May 8, 2000

Dear Ms. Wilk:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with

the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on the labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number: K000062

Device Name: Cordis TrapEase Permanent Vena Cava Filter and Introduction Kit

Indications for Use: The Cordis TrapEase™ Permanent Vena Cava Filter is indicated for the prevention of recurrent pulmonary embolism via percutaneous placement in the inferior vena cava in the following situations: pulmonary thromboembolism when anticoagulants are contraindicated, failure of anticoagulant therapy in thromboembolic diseases, emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced and chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
And Radiological Devices

510(k) Number K000062